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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,113	09/20/2006	Eric Jonsen	US040147US	1777

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
BEHRINGER, LUTHER G	
ART UNIT	**PAPER NUMBER**
3766	

MAIL DATE	DELIVERY MODE
11/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,113	JONSEN ET AL.	
	Examiner	Art Unit	
	LUTHER G. BEHRINGER	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-16,18-21 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-16,18-21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the communication received on 09/25/2008 concerning application no. 10/599113 filed on 09/20/2006.

Response to Arguments

2. Applicant's arguments filed 09/25/2008 have been fully considered but they are not persuasive. Applicant argues the importance of a rigid release liner versus a flexible release liner in a tandem electrode package. All other elements that applicant argues are admitted by the applicant as well known in the art, with examples given. The choice of using a rigid release liner versus a flexible release liner is considered obvious since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim(s) 1 – 3, 7, 18, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Walters (US 5,916,244)**.

Regarding **claim 1,** Walters discloses an electrode comprising: an electrode body having a first and second side, wherein the first side comprises a flexible moisture barrier layer comprising a heat-sealable material, **16**, and the second side comprises a

conductive layer, **24**; an electrically conductive gel layer disposed on the electrode body and which is further in electrical communication with the conductive layer, *hydrogel sheet* **38** (Fig. 2; Col. 3, Lines 20 – 28) the periphery of the heat-sealable moisture barrier extending beyond the periphery of the gel layer; but fails to disclose a rigid release liner heat-sealed to said flexible barrier layer around a periphery of said gel layer.

5. Walters discloses the claimed invention except for a rigid release liner. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a rigid release liner, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With regard to **claim 2,** Walters discloses wherein the heat-sealable material comprises a thermoplastic polymeric material (Col. 2, Lines 48 – 50).

Regarding **claim(s) 3 and 20,** Walters discloses wherein the flexible barrier layer further comprises a vapor or air barrier material comprising a polymeric film or sheet, a foil material, or a coated substrate comprising a metal, textile, paper, or non-woven material coated with a polymeric material, *plastic* (Col. 3, Lines 48 – 50).

With regard to **claim 7,** Walters discloses wherein the electrode further comprises a lead wire that is connected to the flexible barrier layer of the electrode and which electrically connects the electrode to a medical device (Col. 2, Lines 38 – 45).

Regarding **claim 18,** Walters discloses a self-storing electrode system comprising: first and second electrode bodies each having a first and second side,

wherein the first side comprises a flexible moisture barrier layer having a heat-sealable periphery, **16**, and the second side comprises a conductive layer, **24**, which does not extend to the periphery of the moisture barrier layer; an electrically conductive gel, **38**, disposed on each of the electrode bodies which is in electrical communication with the conductive layer of each electrode; and a lead wire, **12**, electrically coupled to each electrode by means of a path that does not disrupt the moisture integrity of the release liner seal (Figs. 1 and 2) but fails to disclose a rigid release liner, **44**, sealed by a heat seal to the periphery of the flexible moisture barrier layer to enclose, protect and prevent desiccation of the gel layer.

6. Walters discloses the claimed invention except for a rigid release liner. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a rigid release liner, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

With regard to **claim 23,** Walters discloses wherein the lead wire, **12**, is connected to the conductive layer of the electrode for electrically connecting the electrode to a medical device (Fig. 2).

7. Claim(s) 4, 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Walters (US 5,916,244)** in view of **Keusch et al. (US 4,989,607, herein Keusch)**.

With regard to **claim 4,** Walters fails to disclose wherein the flexible barrier layer further comprises a vapor or air barrier material comprising a fluoropolymer film.

However, Keusch teaches wherein the flexible barrier layer further comprises a vapor or air barrier material comprising a fluoropolymer film (Col. 13, Lines 46 – 49).

8. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of using a material to create a vapor or air barrier to achieve sterility. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Walters to include the vapor or air barrier as taught by Keusch, since maintaining a sterile medical device aids in the prevention of transmission of disease.

9. Keusch discloses the claimed invention except for the fluoropolymer film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fluoropolymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Regarding **claim(s) 5 and 21,** Walters in view of Keusch discloses wherein the flexible barrier layer comprises a laminate comprising a first layer of a heat-sealable layer comprising polyethylene (Walters: Col. 2, Lines 48 – 50) disposed over a second layer of a vapor barrier comprising a fluoropolymer film (Keusch: Col. 13, Lines 46 – 49).

10. Claim(s) 6 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Walters (US 5,916,244)** in view of **Heath (US 4,419,998)**.

With regard to **claim 6,** Walters fails to disclose wherein the conductive layer comprises a metal sheet or foil, a conductive ink, or a laminate comprising a metal component disposed over a polymeric substrate.

However, Heath teaches wherein the conductive layer comprises a metal sheet or foil, a conductive ink, or a laminate comprising a metal component disposed over a polymeric substrate (Col. 6, Lines 20 – 25).

11. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of disposing a conductive layer over a polymeric substrate to reduce potential shocks to the person delivering therapy. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Walters to include disposing a conductive layer over a polymeric substrate as taught by Heath, since it would make the device safer to operate.

Regarding **claim 19,** Walters in view of Keusch discloses wherein the release liner seal further comprises a heat-seal formed between the flexible barrier layer and the release liner (Col. 13, Lines 46 – 49).

12. Claim(s) 9 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Walters (US 5,916,244)** in view of **Keusch et al. (US 4,989,607, herein Keusch)** in view of **Olson et al. (US 5,817,151, herein Olson)**.

With regard to **claim 9**, Walters in view of Keusch discloses an electrode system comprising: wherein each electrode comprises an electrode body having first and second sides (as stated above), wherein the first side comprises a flexible moisture barrier layer having a sealable periphery (Keusch: Col. 13, Lines 46 – 49) and the

second side comprises a conductive layer, and an electrically conductive gel layer interposed between the conductive layer and the non-conductive release liner (as stated above), wherein the periphery of the moisture barrier layer of each electrode is sealed to the release liner(as stated above) but fails to disclose a pair of electrodes disposed on opposite sides of a rigid non-conductive release liner.

However, Olson teaches a pair of electrodes disposed on opposite sides of a non-conductive release liner (Figs. 1 and 5; Col. 2, Lines 2 – 9).

13. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of disposing both electrodes on opposing sides of a release liner to achieve more compact packaging and electrical conductivity between the electrodes. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Walters in view of Keusch to include disposing both electrodes on opposing sides of a release liner as taught by Olson, since it would make a more compact electrode package and allow electrical conductivity between the electrodes.

14. Walters in view of Keusch in view of Olson discloses the claimed invention except for a rigid non-conductive release liner. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a rigid non-conductive release liner, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Regarding **claim 10,** Walters in view of Keusch in view of Olson discloses wherein the electrodes are further in electrical contact with each other through a conductive element that is disposed within the non-conductive release liner and which is in electrical contact with both electrodes through said gel layer (Col. 2, Lines 2 – 9).

With regard to **claim 11,** Walters in view of Keusch in view of Olson discloses wherein each electrode further comprises a lead wire, **12**, that is connected through said first side to said second side of the electrode and which electrically connects the electrode to a medical device (Walters: Fig. 2).

Regarding **claim 12,** Walters in view of Keusch in view of Olson discloses wherein the lead wire is electrically connected to the conductive layer and the electrically conductive gel by a connector comprising a rivet, **18**, ring tung terminal, staple, grommet, screw, bolt, or other electrically conducting fastening means that extends from the flexible non-conductive release liner through the conductive layer (Walters: Fig. 2).

With regard to **claim 13,** Walters in view of Keusch in view of Olson discloses wherein the electrode further comprises an insulation layer, **22**, interposed between a portion of the conductive layer and the non-conductive release liner, wherein the insulation layer protects an operator of the electrode from physical contact with the connector which is electrically connected to an electrical source (Walters: Fig. 2).

Regarding **claim 14,** Walters in view of Keusch in view of Olson discloses wherein the non-conductive release liner comprises a polymeric sheet, coated paperboard, or foam, (Keusch: Col. 14, Lines 35 – 39).

With regard to **claim 15,** Walters in view of Keusch in view of Olson discloses wherein the non-conductive release liner comprises a material treated with an adhesion-reducing agent comprising a surface-treated polymeric sheet comprising siliconized polyethylene, polypropylene, polyester, acrylate, polycarbonate, or wax or plastic coated paperboard or foam (Col. 3, Lines 27 – 34).

Regarding **claim 16,** Walters in view of Keusch in view of Olson fails discloses wherein the conductive layer comprises a laminate comprising tin foil and polyester.

15. Walters in view of Keusch in view of Olson discloses the claimed invention except for creating the conductive layer having a tin foil and polyester laminate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a conductive sheet having a tin foil and polyester laminate, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Shepard (US 3,556,105)** is cited for its relevance to heat sealing medical electrodes.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

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